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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,986	01/17/2002	Richard John Warby	12654-38018	5632

7590 05/20/2003  
Smith, Gambrell & Russell, LLP  
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1850 M Street, N.W., Suite 800  
Washington, DC 20036

EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 05/20/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/047,986	<b>Applicant(s)</b> WARBY, RICHARD JOHN	
	<b>Examiner</b> Darwin P. Erezo	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 15-17, 24, 25 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,576,068 to Caburet et al.

3. **As to claims 15, 16 and 31**, Caburet teaches an apparatus wherein at least a portion of one or more internal surfaces of the apparatus that come into contact with medicament during storage or dispensing (col. 1, lines 6-8) has a layer of one or more cold plasma polymerized monomers (col. 2, lines 57-62) bonded to at least a portion thereof; wherein the apparatus is not a pressurized container of the medicament or a metering valve for a pressurized container; and wherein the monomer is siloxane (col. 2, line 61).

4. **As to claim 17**, Caburet teaches an apparatus wherein at least a portion of one or more internal surfaces of the apparatus that come into contact with medicament during storage (col. 1, lines 6-8) has a layer of one or more cold plasma polymerized monomers.

5. **As to claims 24 and 25**, Caburet teaches the use of polymers from the siloxane family (col. 2, line 61).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 17, 24-25 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/32345 to Ashurst et al. in view of US 5,576,068 to Caburet et al.

8. **As to claims 17**, Ashurst teaches an apparatus wherein at least a portion of one or more internal surfaces of the apparatus that come into contact with medicament during storage or dispensing has a layer of one or more polymerized monomers bonded to at least a portion thereof. Claim 17 is directed towards a product by process claim, i.e., patentable weight is only given to the final product and any structural limitations associated with the final product and not the process associated with making the final product. Therefore, though Ashurst may not teach cold plasma polymerization of the polymer, Ashurst teaches a final end product having said polymerized monomers.

Ashurst is silent with regards to the layer not being a cold plasma polymerized fluorinated hydrocarbon.

Caburet teaches a process of treating packaging element for medical or pharmaceutical use with cold plasma polymerized monomers to prevent adhesion of the medicament to the container. Caburet teaches the polymerized monomer being a nonfluorinated hydrocarbon.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Caburet because it is a mere design choice to use a specific method to produce the end product of an apparatus with polymers bonded to its internal surfaces. Furthermore, Caburet's method makes it possible to obtain a transparent coating which is advantageous from an esthetic standpoint (col. 6, lines 48-51).

9. **As to claims 24 and 25**, Caburet teaches the use of polymers from the siloxane family (col. 2, line 61).

10. **As to claim 27**, it is well known in the art for a metered dose inhaler to have a housing to hold the container, a mouthpiece and a duct connecting the container to the mouthpiece.

11. **As to claim 28-30**, Ashurst teaches that any part of the metered dose inhaler could have a layer of polymerized monomers.

12. Claims 18-23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashurst et al. in view of Caburet et al. and in further view of US 5,349,944 to Chippendale et al.

13. **As to claim 18**, Ashurst teaches the apparatus as being a metered dose inhaler but is silent with regards to the specific components of the inhaler.

Chippendale teaches a metered dose inhaler having a metering valve comprising a valve stem **5** co-axially slidable within a valve member, the valve member and valve stem defining an annular metering chamber, outer and inner annular seals **3,4** operative

between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the metered dose inhaler of Ashurst include the specific components of Chippendale because it is well known in the art to have a metering valve in a metered dose inhaler.

14. **As to claims 19-22**, Ashurst teaches that a part or all of the internal surfaces of the metered dose inhaler could be coated with polymers.

15. **As to claim 23**, Ashurst teaches a gasket in Fig. 1 (between no. 9 and the valve body).

16. **As to claim 26**, Chippendale teaches the metering valve comprising seals, which are synthetic rubber.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Art Unit: 3761

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

dpe  
May 14, 2003

  
WEILUN LO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700